

REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. Applicants acknowledge with appreciation the indication by the Examiner that claims 18 and 21 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-10 and 12-31 are now pending. Claims 1-10 and 12-28 are amended, without prejudice and claim 11 canceled. New claims 29-31 are added.

Claims 18 and 21 have been amended to include all of the limitations of the base claim and any intervening claims.

No new matter is added by this amendment.

It is submitted that these claims are patentably distinct from the prior art cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims and the new claims are found throughout the specification and from the pending claims.

The Office Action states that listing of references to not a proper Information Disclosure Statement (IDS). In response, Applicants respectfully request that the Examiner considers and makes of record U.S. Patent No. 5,585,642 and EP 0779081 A2 cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

Further, the Examiner is respectfully requested that EP 0779081 A2 reference located in the file that was not documented on an IDS should be considered. When an internal search report and copies of the references cited therein are present in the national stage file, the examiner will consider the documents cited in the international search report, without any further action by applicant under 37 C.F.R. 1.97 and 1.98. (*See*, MPEP chapter 600, such as 609, and MPEP chapter 1800, such as 1893.03(g)). Because the NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371 AND 37 CFR 1.494 OR 1.495, mailed December 21, 2001, for the present application indicates that a copy of the international Search Report and copy of the references cited therein were received, Applicants need not provide any action under 37 CFR 1.97 and 1.98. It is therefore respectfully requested that EP 0779081 A2 be made of record and considered.

II. OBJECTIONS TO THE DRAWINGS

The drawings stand objected because they include reference sign(s) not mentioned in the description. Reference sign 22 is now deleted from figures 10, 11, and 12. The amendment to the specification renders the objection regarding reference signs 4, 12, 14, 17, 21, and 26 moot.

Consequently, reconsideration withdrawal of the objections is respectfully requested.

III. 35 U.S.C. §§ 102 AND 103 REJECTIONS

Claims 1-10, 19, 20 and 22-26, are rejected under 35 U.S.C 102(b) as being allegedly anticipated by Nishihara et al. (USP 5,039,867). In addition, Claim 11 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Nishihara alone. Claims 12-17, 27 and 28 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Nishihara alone or in view of Pu (USP 6,034,377). The rejections will be collectively addressed and respectfully

traversed. The cited documents, either alone or in combination fail to disclose, teach, suggest, enable, or provide the motivation for a skilled artisan to practice the instantly claimed invention.

Claims 1 and 19 are now amended to include the limitation of claim 11. The Examiner admits that Nishihara does not disclose “the ionization chamber being located upstream of the energy absorption means”. (Claim 11). Accordingly Nishihara, does not disclose each and every element of claims 1 and 19 and their dependent claims; and the 102 rejection based on Nishihara cannot stand.

Consequently, reconsideration and withdrawal of the § 102 rejection is believed to be in order and such action is respectfully requested.

Claim 11 was rejected as allegedly unpatentable over Nishihara. Nishihara does not teach, enable or suggest an ionization chamber located upstream of the energy absorption means. The Office Action asserts that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to position the ionization chamber upstream of the energy absorption means, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art to one of ordinary skill in the art.” (*Office Action* at 5). But Nishihara provides a dose monitor 710 (Fig. 34) positioned downstream of the range shifter 709 to control the dose of irradiation in a straight forward control manner, for example, step by step and layer by layer.

In sharp contrast, the present invention provides an ionization chamber 16 (Fig. 1) for monitoring the beam intensity arranged upstream of the energy absorption means 7 (Fig. 1) performing a closed loop control of the dose of irradiation, and not a step by step. Further, the energy absorption means reacts to beam variations without delay, unlike Nishihara. Moreover,

local control of dose distribution is possible only when local volume elements are irradiated separately and the dose can be measured by a dosimeter system, such as, an ionization chamber that is upstream to any dose delivery system. Such an active scanning system is the principle of the present invention where an ionization chamber upstream of the dose delivery system controls the dose in each volume element. Accordingly, its not a mere reversal of the essential working parts of a device that would involves only routine skill in the art. Therefore, unlike the passive system provided Nishihara, the present invention provides an ionization chamber upstream of the of the energy absorption means. Such an invention is neither taught nor suggested in, nor enabled by Nishihara.

Claims 12-17, 27 and 28 were rejected as allegedly unpatentable over Nishihara in view of Pu. Pu does not remedy the deficiencies in Nishihara. Pu is relied upon solely that it allegedly suggests a rotating gantry and a stationary target volume carrier. (*Office Action* at 6). The rejections based on the additional reference to Pu should be withdrawn in view of the foregoing discussion.

As mentioned above, Nishihara relates to a method of scanning layer by layer by setting the dose by a straight forward control for n-layers until the irradiation is completed when reaching the total dose, *i.e.*, the deepest layer for scanning. (Fig. 38, flow chart). In contrast, the method of the present invention is based on a depth-staggered scanning of volume elements of a target volume. However, Pu teaches a different function to achieve depth distribution of the dose. For example, Pu provides a mechanical fixed distribution that is determined by the wall thickness in a circumferential direction of the energy modulator (Pu, col. 6, lines 1-4). But in particle therapy with an ion beam, depth dose profiles varying from point to point have to be

performed. Pu does not disclose, suggest, teach or enable such a method. In contrast, the present invention provides changing the depth profile from point to point using an intensity controlled system. Two wedge shaped blocks mounted on a linear motor system moves these wedges to control the energy variation of the beam. The wedges are controlled by a closed loop feed back system that uses particle flux, *i.e.*, the actual beam intensity, as input, unlike Nishihara either alone or in combination with Pu.

Accordingly, the instant invention is not disclosed, taught, suggested in, nor enabled by, Nishihara in combination with Pu.

Further, new claim 31 is also patentable over the cited documents. Specifically, Nishihara provides a pair of wedge shaped energy absorption members 601a and 501b (Fig. 27) driven by drive units 602a and 602b. (Fig. 27). These drive units are electrically connected with a three-dimensional irradiation control unit 711 (Fig. 35). This control unit performs straight forward program to change irradiation step by step and scanning layer by layer (Fig. 37). Such a system has considerable drawbacks (Application, page 2, line 22–page 3, line 12).

In contrast, the present invention includes a high speed linear motor having linear rotors (Fig. 1, Ref. No. 31) mounted on air bearings (Fig. 1, page 15, lines 11-14). This linear motor enables a rapid succession over the whole depth of the target volume, specifically, the depth-staggered scanning of volume elements of the target volume, unlike the known layer scanning of the prior art.

As there is no teaching or suggestion of these claimed elements, or an expectation of success in Nishihara either alone or in combination with Pu, the Section 103 rejection must fail. The Federal Circuit in *In re Fine* was very clear that “obvious to try” is not the standard upon

which an obviousness rejection should be based. And as “obvious to try” would be the only standard that would lend the Section 103 rejection any viability, the rejection must fail as a matter of law.

More specifically, in order to ground an obviousness rejection, there must be some teaching which would have provided the necessary incentive or motivation for modifying the reference’s teaching. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (B.P.A.I. 1993). Further, “obvious to try” is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, the cited document fails to teach, suggest or disclose the instantly claimed invention.

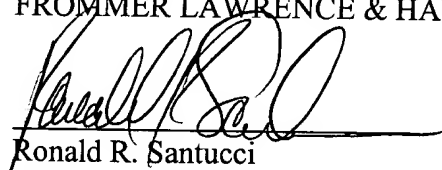
Consequently, reconsideration and withdrawal of the § 103 rejection are believed to be in order and such actions are respectfully requested.

CONCLUSION

By this Amendment, the instant claims should be allowed; and this application is in condition for allowance. Favorable reconsideration of the application, withdrawal of the rejections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By:



Ronald R. Santucci
Reg. No. 28,988
Tel: (212) 588-0800
Fax: (212) 588-0500